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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/823,868	03/30/2001	Robert K. DiNello	22203-712	7040

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EXAMINER

NGUYEN, BAO THUY L

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 12/12/2003

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/823,868

Applicant(s)

DINELLO ET AL.

Examiner

Bao-Thuy L. Nguyen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 October 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 28-31, 36-39 and 42-45 is/are pending in the application.
- 4a) Of the above claim(s) _____, is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 28-31, 36-39 and 42-45 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 8.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

1. Applicant' amendment filed 10 October 2003 has been received. Claims 1-27, 32-35, 40-41 and 46-63 have been canceled. Claims 28-31, 36-39 and 42-45 are pending.

Claim Rejections - 35 USC § 112

2. Claims 28-31, 36-39 and 42-45 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 28 is confusing with respect to the description of the terminal buffer flow zone. It is unclear how this zone function. Claim 28 recites a method where a buffer added to the test strip diffuses toward the terminal buffer flow zone and changes direction and essentially reverse direction. How does the terminal buffer flow zone cause the buffer to change direction? What properties of the terminal buffer flow zone allow this to occur?

Claim 28 is also confusing because it is unclear how two different liquid specimens, i.e. the sample and the buffer solution, added to different ends of a test strip is able to diffuse toward each other and not in one direction, either to the left or right relative to their own location. What property does the test strip possess that allow this to occur? If this is effected by virtue of the placement of the various zones, this should be made clear.

Claims 43 and 44 are confusing because it is unclear where the control zones are located relative to the various test zones, buffer zones and sample zones.

Claim Rejections - 35 USC § 102

3. The rejection of claims 28-45 under 35 USC 102(b) as being anticipated by Clark is withdrawn in view of the amendment to the claims.
4. The rejection of claims 28-45 under 35 USC 102(e) as being anticipated by Thayer is withdrawn in view of the submission of a declaration under 37 CFR 1.132 which shows that the instant invention, although disclosed but not claimed in the Thayer reference, is derived from the inventor of this application and is thus not the invention "by another", e.g. Thayer, Sierra and Wieck did not conceive of the subject matter claimed in the instant invention.

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Double Patenting

5. The rejection of claims 28-35 and 40-45 as obvious over claims 27-41 of US 6,528,323 is withdrawn in view the cancellation some of the claims and the submission of a terminal disclaimer.

Conclusion

6. The claims are free of the prior art.

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

US 6,284,194 B1 discloses surfactant-treated porous reaction membranes to increase sample flow rate and shorten reaction time. However, this method results in decreased assay sensitivities.

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao-Thuy L. Nguyen whose telephone number is (703) 308-4243. The examiner can normally be reached on Tuesday and Thursday from 9:00 a.m. - 5:00 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (703) 305-3399. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 and (703) 305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.


Bao-Thuy Nguyen
Primary Examiner
23 July 2003